minutes at teaching hospitals and 175 minutes at non-teaching hospitals. There were significant variations in duration of routine ED visits across race groups at teaching and non-teaching hospitals. The risk-adjusted results show that the mean duration of routine ED visits for black/African American and Asian patients when compared to visits for white patients was shorter by 10.0 and 3.4 percent, respectively, at teaching hospitals; and longer by 3.6 and 13.8 percent, respectively, at non-teaching hospitals. Hispanic patients experienced 8.7 percent longer ED stays when compared to white patients at non-teaching hospitals. **CONCLUSIONS:** There is significant racial disparity in the duration of routine ED visits, especially in non-teaching hospitals where non-white patients experience longer ED stays compared to white patients. The variation in duration of routine ED visits at teaching hospitals when compared to non-teaching hospitals was smaller across race groups.

HEALTH CARE USE & POLICY STUDIES – Diagnosis Related Group

PHP7
DRG SYSTEM IN ITALY: EVALUATION OF DIFFERENT REIMBURSEMENTS FOR SURGICAL PROCEDURES AT NATIONAL, REGIONAL AND HOSPITAL LEVEL

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OBJECTIVES: The Italian National Health Service (*Servizio Sanitario Nazionale-SSN*) is structured on two levels: the national and regional level. The national government defines the benefits package (essential levels of care, *livelli essenziali di assistenza-LEA*) to which citizens are constitutionally entitled and which each Regional Health Service (*Servizio Sanitario Regionale*-SSR) is responsible for. Since 1997 the regions have been fully autonomous in organizing and managing their SSR, including the definition of DRG tariffs for hospital admissions. The aim of this study is compare the regional differences among tariffs for the main surgical DRGs of each Major Diagnostic Category (MDC). **METHODS:** In order to identify the surgical DRGs with the highest volumes for each MDC, we used the dataset of admissions registered in 2010 by all hospitals (DRG version 24 ICD9-CM), published by the Italian Department of Health (*Ministero della Salute*), and we analyzed the variability among tariffs by calculating their average and standard deviations (the extra-reimbursement has not been considered). **RESULTS:** Average tariffs were calculated starting from the standard regional tariff for each DRG. Comparing the first 10 DRGs, we identified a variation in the average tariff which rose from -1.8% to +22.6% and a standard deviation with a minimum of 425€ and a maximum of 1443€. Further complexity is given by the intra-regional variation by type of hospital, where we observed a variation inside the same region of 82% for the same DRG. **CONCLUSIONS:** The SSN is characterized by a high variability of regional DRG tariffs, also inside the regions. Moreover in Italy there is not a defined procedure to update the classification of DRGs and the related tariffs. Therefore there is a need to establish a systematic periodical review, which should involve all the different stakeholders of SSN, and to share data updated with them about the volume of admissions.

PHP8
SWITCHING THE PERFORMANCE VOLUME LIMIT (PVL) TO DEGRESSIVE FINANCING METHOD IN THE HUNGARIAN DRG-BASED HOSPITAL REIMBURSEMENT BETWEEN 2009-2012

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OBJECTIVES: The aim of our study was to investigate the financial effects of switching from the so-called performance volume limit (PVL) to degressive financing method in the Hungarian DRG-based hospital financing. **METHODS:** The data in our analysis were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency. We examined mainly the period between 2009 and 2012. The difference in hospital reimbursement between the preannounced DRG reimbursement rate and degressive cap (upper ceiling) was calculated both on national level and in the case of the Clinical Center of the University of Pécs. **RESULTS:** The ratio of partially paid [based on preannounced performance base-fee (PPBF) or performance volume limit (PVL) financing method] active inpatient cost-weights to total cost-weights varied extremely between 2009-2012. In the case of PPBF financing in 2009, 25-30% of the total national performance fell under floating fee structure, resulting in a monthly change in the monetary (Hungarian Forint, HUF) value of a DRG cost-weight. In the case of degressive PVL from 2011 onwards, one to seven percent of the national performance fell in the degressive zone, with a prefixed value of HUF 45,000/cost-weighs. For the Clinical Centre of the University of Pécs, this partial reimbursement resulted in a large financial deficit in 2009, when PPBF was applied. In 2010 and 2011, the deficit of the University of Pécs lessened to some extent compared to 2009; however, it was still rather high (HUF 1.46 and HUF 1.3 billion, respectively). Due to partial health insurance reimbursement, the University of Pécs realized HUF 8.1 billion revenue losses between 2004 and 2012. **CONCLUSIONS:** Application of preannounced performance base-fee rendered institutional financing nearly incalculable. Renewed introduction of degressive performance volume limit in 2011 made institutional financing more calculable; however, it failed to entirely stop source withdrawal.

HEALTH CARE USE & POLICY STUDIES – Disease Management

PHP9
TRENDS IN USE OF HEALTH ECONOMIC EVIDENCE FOR DEVELOPING CLINICAL GUIDELINES

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OBJECTIVES: The recent reforms and policy changes have increased the cost pressures on all health care stakeholders, including clinical experts. In the past, clinical guidelines were developed independent of cost or economic considerations. However, increasingly, more clinical guidelines are mentioning cost concerns and referring to economic data in new recommendations. The objective of this study was to analyze trends in the use of health economic information for developing clinical guidelines. **METHODS:** To understand trends in use of health economic information we conducted targeted search for clinical guidelines, expert recommendations, and consensus statements with specific mention of "cost" or "economic" or related terms. A systematic literature search was undertaken for the databases Pubmed, Google Scholar and Cochrane. The guidelines published between 2003-2012 were included. For guidelines which met the search criteria, data was collected for the name of the authors, indication, year of publication, country/region, and context of use of cost/economic evidence. **RESULTS:** Sixteen clinical guidelines published between 2003-2012 met the inclusion criteria for specific mention of cost/economic evidence. More than 50% of these guidelines were published between 2006-2012. For indication, 3 out of 16 guidelines were for diabetes, while the rest were for different indications. In these16 guidelines "cost effectiveness" was mentioned 14 times, either referencing cost-effectiveness data or to mention the importance of such data for selecting treatment options. The guidelines commonly cite high cost of disease or high economic burden as one of the considerations for developing new recommendations (11 out of 16). Another term that was commonly used by these guidelines was "cost-benefit," which was mentioned 5 times in these guidelines. Notably, QALY was rarely mentioned (1 out of 16 times) in these guidelines. **CONCLUSIONS:** This analysis suggests that some clinical experts groups are increasingly showing willingness to use and incorporate health economic information for developing new recommendations.

HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP10
ANALYSIS OF THE WAXMAN-HATCH ACT PHARMACEUTICAL PATENT EXTENSIONS (1984-2012)

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OBJECTIVES: The Drug Price Competition and Patent Term Restoration Act of 1984 (Waxman- Waxman Act - WHA) established a patent extension system that allows sponsors of new drugs (NDAs) and biologic applications (BLAs) approved by Food and Drug Administration (FDA) to recover part of the patent time dedicated to clinical trials and to the FDA drug review process. The maximum extension is 5 years and the effective patent life from approval to patent expiration cannot exceed 14 years. We assessed the characteristic of drugs and biologics that had a patent extension in the period 1984-2012 and examined the patent life timeline from clinical trials to regulatory review, and from marketing authorization to patent expiration (i.e. effective patent life). **METHODS:** Data were derived from the FDA, the US Patent and Trademark Office, and the US Federal Register. Descriptive analyses were performed. T-test was used to assess differences in averages. Significant level was set at 0.05. **RESULTS:** The USPTO listed 499 pharmaceuticals with patent extensions in the study period; 453 NDAs (90.8%), 38 BLAs (7.6%), and 9 vaccines (1.8%). Drug regulatory and patent information was available for 323 pharmaceuticals (287 NDA, 32 BLA and 4 vaccines). The average±stdev patent extension was 2.7±1.4 years (median=2.2 years; 95% CI=2.62.8). The extension was longer for vaccines (3.7±1.3 years) than for NDAs (2.7±1.4 years) and BLAs (2.4±1.5 years). The average clinical trials time was 5.9±3.1 years, being similar for NDAs, BLAs and vaccines. The average FDA review time was 1.7±1.3 years (higher for vaccines 2.6±2.5 years). The average length of the effective patent life was 8.7±7.0 years without patent extensions and 11.7±6.8 years after the extensions. **CONCLUSIONS:** A large number of pharmaceuticals were granted patent extensions in the US. The WHA significantly increased the effective patent life of pharmaceuticals.

PHP11
PRELIMINARY STUDY ON DEVELOPMENT OF BUDGET IMPACT ANALYSIS GUIDELINES IN KOREA: THE COMPARISON OF GUIDELINES ON BUDGET IMPACT ANALYSIS FOR HEALTH TECHNOLOGIES

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OBJECTIVES: A budget impact analysis(BIA) is a useful tool for a health care decision maker in estimating the financial impact of the new technology. In Korea, the content and presentation of results of the BIA have been proposed but detailed guidance on methods for BIA are not yet available. To evaluate the international landscape of BIA guidance, we compared guidelines of BIA outside of Korea. **METHODS:** A literature review was performed. Research for guidelines was based on data published in latest official papers or reports from ISPOR and national institutes in Canada, Ireland, and Poland. **RESULTS:** In all guidelines, the recommended perspective was that of public purchaser. A time horizon of 2-5 years was considered to be desirable. It was stated that data on a technology and its use should be included in BIA, which is helpful for decision makers. Published guidelines provided a similar description of target population, but it was different whether or not off-label usage of drugs was included in assumption of population size. The approaches to measurement and evaluation of costs varied in different regions. The costing included direct costs associated with the technology in four guidelines but items of other costs were specified

differently. When analysts report the results of study, both total and incremental budget impact should be presented for each year of the time horizon. Sensitivity analysis was emphasized in order to identify the uncertainty within the analytic framework. The guidelines suggested that the discounting is unnecessary and encourage model validation except those of Poland. **CONCLUSIONS:** This review discovered that Canada, Ireland, Poland, and ISPOR BIA guidelines were consistent in basic analytic framework, but details were depended on payer perspective and regional specificity. This study is expected to help to develop Korean BIA guidelines.

PHP12

A COMPARISON OF NEW DRUGS APPROVED BY THE EMA AND THE FDA IN 2006-2011

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OBJECTIVES: The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) have different regulatory systems for the review and approval of new drugs. This study reviewed and compared the characteristics of priority review new pharmaceuticals (i.e. new molecular entities -NME- and new therapeutic biologics -BLA-) approved by EMA and the FDA in the period 2006-2011. **METHODS:** Data were extracted from the FDA and EMA websites. Dates of application and approval and orphan status information were extracted from the FDA approval letters and the EMA public assessment reports. Descriptive statistics were used to compare the approval processes and characteristics of both systems; t-test was used to assess differences in average review time. Significant level was set at 0.05. **RESULTS:** A total of 47 drugs (34 NME and 13 BLA) were approved by both regulatory agencies in the study period. BLAs were submitted to the FDA 22±166 days earlier (median=10 days) and approved by the FDA 211±145 days earlier (median=168 days) than the EMEA. NMEs were submitted to the EMA 229±832 days earlier (median=33) and approved by the EMA 97±884 days earlier (median=173 days) than the FDA. The average review time was statistically significantly lower (p<0.001) for the FDA 258±200 days (median=184 days) than for EMA 406±96 (median=407 days). The number of products with orphan designation at the time of the first approval was higher in the FDA (n=20) than in the EMA (n=15). EMA granted orphan designation at the time of approval to two products that did not have orphan designation in the US. **CONCLUSIONS:** There are significant differences in the time elapsed between the filing and the approval of priority review products in the US and EU. Orphan designation also varied between the two regulatory systems. Harmonization of the regulatory systems could facilitate timely approval of essential pharmaceuticals.

PHP13

AN EVALUATION OF THE ASSOCIATION BETWEEN AN FDA SUICIDALITY WARNING AND ANTIEPILEPTIC MEDICATION USE IN A STATE MEDICAID PROGRAM

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OBJECTIVES: In January 2008, the Food and Drug Administration (FDA) communicated concerns and later in May 2009, issued a warning about an increased risk of suicidality related to all antiepileptic drugs (AEDs). The purpose of this study is to evaluate the association between an FDA suicidality warning and AED use among Oklahoma Medicaid enrollees diagnosed with epilepsy and/or psychiatric disorder(s). **METHODS:** A longitudinal interrupted design was conducted to study Oklahoma Medicaid claims data from January 2006 through December 2009. A total of 13,126 individuals met the study criteria: diagnosis with epilepsy and/or psychiatric disorder(s) and filling of at least one AED prescription. A segmented logistic regression model compared the level and trend in the log odds of AED use among three time periods: a baseline period of 25 months (Jan. 2006 - Jan. 2008) before the FDA warning; the 16 months (Feb. 2008-May 2009) during the FDA warning; and the 7 months (June 2009-Dec. 2009) after the FDA warning. Generalized estimation equations (GEE) were used to estimate trends in AED utilization while adjusting for several covariates. **RESULTS:** There was a statistical increase in the trend, expressed as a monthly change in log odds of AED use, before the FDA warning period (p<0.0001). However, this trend decreased by 34% (99% CI: 10.2% to 57.6%, p=0.0002) during the FDA warning period when compared to the baseline trend. This decrease in trend did not remain significant after the FDA warning period (p=0.2957). Compared with the baseline level of AED utilization before the FDA warning period, the log odds of AED utilization level also decreased by 22% (99% CI: 1.9% 42.2%, p=0.0048) after the FDA warning period. **CONCLUSIONS:** The FDA suicidality warning was associated with a reduction in overall AED use among this population.

PHP14

THE IMPACT OF KOREAN PROSPECTIVE DRUG UTILIZATION REVIEW PROGRAM ON THE RATE OF DRUG-DRUG INTERACTIONS

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OBJECTIVES: Since December 2010, online computerized prospective DUR(pDUR) has been implemented in Korea. pDUR involves the review of each prescription before the medication is dispensed to the individual patient. The pDUR is performed electronically by Health Insurance Review & Assessment Service (HIRA), which is a Korean governmental agency, and then HIRA provides medical institutions and pharmacies with information that can be helpful to them in preventing potential drug problems such as drug/drug interactions or ingredient duplication. The aim of this study was to assess the impact of the Korean pDUR implementation on the rate of drug-drug interactions (DDIs) using claims data of HIRA. **METHODS:** A before-after comparison of the prevalence of DDIs was conducted, using HIRA administrative claims data from medical institutions from January 2010 to December 2011. In addition, a paired t-test was applied to examine the difference between the pre- and post-pDUR. The analysis unit was the prescription issued and main outcome measures were the rates of DDIs within- (control group) or between- physician encounters. **RESULTS:** The mean DDIs rates (pre-test and post-test) within patient visits were 0.29‰ and 0.22‰, respectively. The mean rates of DDIs between visits were 0.94‰ (before) and 0.80‰ (after). As a result of the t-test, we found that DDIs rate between encounters decreased significantly (t=3.04, p=0.0026) after the implementation of pDUR, whereas there is no significant reduction within encounters (t=1.15, p=0.2518). With respect to the prevalence of DDIs between drug groups, the most dramatic reduction was occurred between HMG CoA reductase inhibitors and anti-fungal agents. **CONCLUSIONS:** It seems effective that giving a direct feedback to prescribers by a prospective DUR. Further research is needed to assess the impact of DUR to final outcomes such as hospitalization.

PHP15

"SAFE AND EFFECTIVE" VERSUS "REASONABLE AND NECESSARY": IS THE DECK STACKED AGAINST DEVICES?

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OBJECTIVES: US Food and Drug Administration (FDA) approval does not necessarily equate with coverage by the Centers for Medicare and Medicaid Services (CMS) or private payers for a device or a drug. The FDA is charged with determining the safety and efficacy of medical products. In contrast, payers are primarily concerned with whether medical products are reasonable and necessary. As health care costs continue to rise, manufacturers face increasing pressures to justify product prices and provide rationale to payers to support favorable funding decisions. Our objective was to review coverage decisions for devices and reasons for noncoverage to determine whether payers are expecting more pharmaceutical-like evidence. **METHODS:** We reviewed Washington State Health Technology Assessment (HTA) decisions for therapeutics from 2007 through 2012. Reasons for noncoverage were classified as lack of clinical efficacy or other. **RESULTS:** We identified 22 therapeutic HTA reviews, of which 11 included some level of noncoverage determination for the product or procedure. The reason for noncoverage was stated as a perceived lack of clinical efficacy evidence. For example, a 2008 decision against implantable infusion pumps for the treatment of chronic noncancer pain was based partly on the fact that "[t]he only kind of evidence about whether implantable infusion pumps are effective for patients with chronic noncancer pain comes from uncontrolled case series." Such statements demonstrate the disparity between FDA approval of devices and payer expectations for efficacy evidence to support coverage decisions. Payer evidence requirements for medical devices continue to move closer to those historically associated with pharmaceuticals. **CONCLUSIONS:** No roadmap exists for determination of reasonable and necessary levels of evidence for device-coverage decisions. FDA and payer evidence requirements are not aligned. Moving forward, evidence-generation efforts for devices will, in most cases, have to exceed FDA requirements in order for payer evidence needs to be met.

PHP16

REVIEWING AND REFINING THE CONCEPTUAL FRAMEWORK FOR THE CURRENT DRUG DEVELOPMENT PARADIGM (CDDP)

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OBJECTIVES: To examine how five global pharmaceutical companies are currently developing comparative effectiveness research (CER) and relative effectiveness (RE) evidence. **METHODS:** We followed two parallel steps. First, a targeted literature review was performed. Second, a semi-structured interview program was conducted with 19 senior key informants (KI) across the five companies. After analyzing the interview results using systematic content review, we merged these findings with the literature review to extrapolate the final study results. **RESULTS:** We found a clear recognition of the growing importance of CER/RE within the industry, although the KIs differed regarding whether this was a disruptive change or simply an extension of traditional outcomes research efforts. Most viewed the payer/HTA community as the biggest driver of CER/RE evidence needs, rather than patients or clinicians. Nearly all KIs stated that their organizations already incorporate CER/RE criteria into their current drug development paradigm (CDDP), but differed in the timing (phase of development), degree of investment, whether CER/RE considerations influenced go/no-go decisions and type of product. Barriers to adaptation of the CDDP included historic prioritization of regulatory approval; concerns about increased study costs and complexity; heterogeneity of stakeholder evidence requirements; and difficulty integrating across departments. Facilitators of change included increasing CER/RE expectations of payers/HTA bodies and having senior management serve as an internal CER/RE champion. Most interviewees believed that CER/RE would play a greater role in drug development by 2020, particularly driven by payer/HTA demands for evidence of value. **CONCLUSIONS:** Our interviews revealed that there has been a spectrum of response to the perceived need for CER/RE data that involves altering the CDDP in a variety of important ways to include primarily the information needs of payers and HTA bodies. These changes to the CDDP are projected to grow